

**University of North Carolina at Chapel Hill
Consent to Participate in a Research Study**

Adult Participants

Consent Form Version Date: 05/25/2020

IRB Study # 20-1206

Title of Study: Development of salivary antibody assay for population surveillance of SARS-CoV-2 infections

Principal Investigator: Dr. Tim Wade

Principal Investigator Department: US Environmental Protection Agency

Principal Investigator Phone number: (919) 966-8900

Principal Investigator Email Address: wade.tim@epa.gov

Funding Source and/or Sponsor: US Environmental Protection Agency

Study Contact Telephone Number: (919) 966-8900

Study Contact Email: epistudies@epa.gov

CONCISE SUMMARY

When you are infected with a virus your body makes antibodies to fight off the infection. These antibodies can be measured to find out if a person has been infected with a particular virus. The goal of this study is to develop and validate a screening test for antibodies in saliva that can tell whether people have been infected with the new coronavirus, SARS-CoV-2.

We ask you to participate in this study because you have been infected with SARS-CoV-2. You are being asked to provide two saliva samples and return them to our research office. The samples will be simple and painless to collect and will only take a few minutes. You will also complete a short questionnaire about what symptoms you have had and some basic information such as your age and the date when you tested positive for SARS-CoV-2.

There are no risks to participating in this study greater than those from daily living. Saliva samples are simple and painless to collect. You are not being asked to give us sensitive personal information like your driver's license number or social security number. We will provide saliva sampling kits, a shipping container and pre-paid return label to return the samples to our office.

If you are interested in learning about this study, please continue to read below

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study.

What is the purpose of this study?

The goal of this study is to develop a way to test saliva for antibodies that can tell whether people have been infected with the new coronavirus, SARS-CoV-2. You are being asked to be in the study because you were infected with the new coronavirus SARS-CoV-2. Minors under the age of 18 are not eligible to participate.

Are there any reasons you should not be in this study?

You should not be in this study if you have not recently been infected with the new coronavirus or if you do not want to collect saliva samples and provide them to us. You should not participate in this study if you are under 18 years of age. You should also not participate in this study if you cannot read and write in English and if you don't currently live in the United States.

How many people will take part in this study?

Approximately three hundred people will take part in this study.

How long will your part in this study last?

Your participation in this study will take about 1 hour to collect your saliva samples, complete a short questionnaire, pack them up and send them back to us. We will ask some of you to give three more sample collections over the course of a year. We may contact you again at a later time to see if you are interested in taking part in other studies.

What will happen if you take part in the study?

If you agree to take part in this study, our research team will contact you and provide you with the collection materials you need. You will provide two samples and complete one short survey. You will provide two types samples. The first type of sampler is a small sponge attached to a handle. To collect this sample you will gently rub your gums with the sponge until it is completely soaked, for about 1 minute. The second type of sampler is a small tube attached to a collection vial. You will drool saliva into the tube until the collection vial is full, which will take about 2-3 minutes. You might need to wait a few minutes between the samples if your mouth is dry. You will also complete a short questionnaire about what symptoms you might have had and some basic information, such as your age and where you live. We may contact you later to see if you are interested in taking part in other studies.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study. We hope that by developing a new way to test for the new coronavirus infection we can better understand how to prevent these outbreaks in the future and who might be at the biggest risk for severe illness and future infection.

What are the possible risks or discomforts involved from being in this study?

There are no known risks for collecting saliva samples beyond those faced in daily living. You might experience a short feeling of discomfort. You might also experience a little bit of bleeding from your gums,

How will information about you be protected?

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent. Records, including the information entered from your questionnaire and the results of the saliva tests will be stored in private password-protected computer network, accessible only to the research team. Individually personally identifying information such as your name and address will be stored separately from the research data and linked by a random identification number.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, the Environmental Protection Agency will take steps allowable by law to protect the privacy of personal information.

Will you receive results from research involving your specimens?

Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results. The test we are trying to develop is not for clinical diagnostic purposes. It is intended for research only and it has not been approved by the Federal Drug Administration to diagnose COVID-19

infections. No genetic testing will be done on the sample you provide us. The samples you provide us will not be used for commercial profit.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will receive \$25 for being in this study. For those of you who provide three more samples over the course of one-year, you will receive an additional \$25 for each collection. We will mail you a check after we receive your samples and completed questionnaire.

Will it cost you anything to be in this study?

You may have travel costs related to finding a shipping center or drop-box to return your saliva samples.

Who is sponsoring this study?

This research is funded by the US Environmental Protection Agency. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I voluntarily agree to participate in this research study.